

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION**

**BUCKEYE TRANSPLANT SERVICES,
LLC,**

Plaintiff,

-v-

**UNITED NETWORK FOR ORGAN
SHARING,**

Defendant.

Civil Action No.

3:23-cv-00427-REP

**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

Plaintiff Buckeye Transplant Services, LLC (“Buckeye”) seeks emergency injunctive relief to enjoin Defendant United Network for Organ Sharing (“UNOS”) from (a) requiring Buckeye to cease operation of its Rapid Organ Procurement Tool, (b) requiring Buckeye to delete data, (c) suspending Buckeye’s access to the OPTN, or (d) attempting to monopolize the U.S. market for providing transplant centers with data regarding the centers’ past decisions to accept or not accept organs for transplant. Absent the Court’s intervention, Buckeye will be forced to accede to UNOS’ demands that Buckeye stop using the Rapid Organ Assessment Tool, to the detriment of the transplant hospitals and patients who depend on its capabilities, and irreversibly delete years of data gathered for Buckeye’s organ transplant center clients, or else be barred from accessing the OPTN as early as July 5, 2023, as UNOS has threatened.

Today, Buckeye has UNOS-approved access to the OPTN in order to assist Buckeye’s customers, transplant centers across the country who must rapidly assess organs that become available for transplant to determine if the organs can be offered to patients in need. UNOS does

not contend that Buckeye is not authorized to access the OPTN. Rather, at issue in this dispute is whether Buckeye may continue to use its technological tools to provide efficient and accurate organ coordination services to its clients. Buckeye contends that UNOS' interpretation of its terms and policies is not supported by their text or prevailing industry practice. UNOS confirmed as much when it emailed all OPTN users on Friday, June 30, referencing its terms of use but modifying the language to make it seem like those terms supported UNOS' position in its dispute with Buckeye. Nevertheless, UNOS' July 5 deadline for Buckeye looms.

Buckeye's request is uncomplicated and essential to ensuring that patients in need of transplants have the same chance of receiving life-saving organs on Thursday, July 6 that they do today. This motion presents the classic effort to preserve the status quo while the Court resolves the parties' disagreement about the meaning of UNOS' terms of use and policies. The Court should enjoin UNOS from causing Buckeye and the patients its transplant center customers serve irreparable harm.

STATEMENT OF FACTS

I. The Organ Donation and Transplant Process

In the United States, organ donations and transplants are coordinated through a national network of organ procurement organizations ("OPOs"), transplant centers, and service providers. UNOS operates the technological system for matching donors with patients waiting for an organ transplant through OPTN. Declaration of Jared Ackley ("Ackley Decl."), ¶ 4. When an organ from a deceased donor becomes available, an OPO facilitates the process at the donor's hospital and gathers detailed information about the available organs to transmit to UNOS. That information is then processed and made available through the OPTN in the form of an "offer" to transplant centers with potential recipient patients on the organ transplant waiting list. *Id.* at ¶ 5.

Upon receipt of an organ offer, a transplant center must analyze and evaluate the suitability of the organ before making a decision on whether to accept or decline it. This decision requires retrieving and analyzing a large volume of information from the OPTN systems. If the organ matches the transplant center's criteria, the information is communicated to the physicians, decision makers, and surgeons who would ultimately perform the transplant for a final decision. If an organ is declined, it is offered to the next transplant center on the list, and so on, until the organ is either matched, is determined to no longer be viable for transplant, or is declined by every center on the match list. *Id.* at ¶ 6.

Time is of the essence in this process of transplant coordination, as organs remain viable for only a short period of time following the death of the donor, and delays in transplant centers' response time significantly increases the risk that organs will become unviable or otherwise unavailable for transplant. *Id.* at ¶ 7. Transplant centers also must act quickly on organ offers so that the centers can consider more offers. Timely considering more organ offers increases the number of opportunities a transplant center has for their listed recipients. Patients do not have time to waste. *Id.* at ¶ 8.

From the time that a transplant center receives notification of an offer, it typically has between 30 minutes to an hour (depending on the status of its potential recipient on the transplant list) to respond to the offer. If a transplant center fails to respond within the allotted time frame, it may be bypassed and the offer moved on to the next candidate. The more transplant centers that decline or fail to respond to an offer, the longer the delay in matching the organ with a recipient, which increases the risk that the organ will not be transplanted at all. *Id.* at ¶ 8. Transplant centers may be notified of new organ offers at all hours of the day. Due to the time-sensitive nature of the organ matching process, all transplant centers are required to have

transplant personnel—whether an internal employee or a third-party contractor—available at all times to receive, evaluate, and process organ offers. *Id.* at ¶ 9.

II. Buckeye Helps Transplant Centers Make Life-Savings Decisions Faster

Buckeye is the nation's leading provider of specialized services for transplant centers to facilitate the organ donation process. Buckeye's clients include dozens of prominent hospitals and medical centers that rely on Buckeye's services at various stages of the donor transplant process. Buckeye began partnering with transplant centers across the United States in 2008. Ackley Decl. ¶ 3. Buckeye has over 150 transplant coordinators on staff and a large dedicated team of technical staff. Buckeye's coordinators have extensive years of organ placement or transplant experience and are made up of Registered Nurses, Respiratory Therapists, and Procurement Transplant Coordinators. *Id.* at ¶ 10. Buckeye's industry and technical expertise have enabled it to add significant value to the transplant coordination process. In 2022, Buckeye assisted in the facilitation of 5,906 organ transplants at its client transplant centers—accounting for over 16% of all deceased donor transplants that took place in the United States last year. *Id.* at ¶ 11.

At a high level, Buckeye's services and technological capabilities enable its client transplant centers to screen and respond to offers more quickly and efficiently. Among other services, Buckeye assists its clients in the process of evaluating and responding to organ offers by receiving notifications of new offers, evaluating data regarding the available organ, and identifying acceptable offers based upon the criteria established by the client transplant center. *Id.* at ¶ 12. For the clients of Buckeye's offer screening services, Buckeye acts essentially as the transplant center's outsourced transplant personnel, providing front-line intake of new offers, retrieving and analyzing information from the OPTN systems, and determining whether the offer meets the transplant center's criteria for potentially acceptable organs. In this capacity, Buckeye

accesses the OPTN systems as an authorized third party, on behalf of the member transplant center. *Id.* at ¶ 13.

Many of Buckeye's clients rely on Buckeye to track and report on the transplant center's offer decision data, which are then used by the transplant centers to conduct internal reviews with their transplant physicians and other decision-making personnel in order to analyze and improve their organ offer evaluation process. Buckeye's clients have also relied on Buckeye's data analytics and processing capabilities to provide reports in connection with information that the transplant centers then relay to UNOS and other entities for transplant program improvement. *Id.* at ¶ 16.

At issue in this dispute are Buckeye's front-line offer screening and decision review services—two of the most important services utilized by Buckeye's clients to facilitate and improve their organ transplant processes. Specifically, UNOS has demanded that Buckeye discontinue two of its technological tools—the Rapid Organ Assessment Tool and the Operational Assessment Tool.¹

A. The Rapid Organ Assessment Tool

The Rapid Organ Assessment Tool is a web browser plug-in designed to enable the user to quickly and accurately analyze the large volume of information that needs to be reviewed in the evaluation of an organ offer. Ackley Decl. ¶ 19. The tool is deployed solely on Buckeye's internal web browser. It does not reside on or through any UNOS system. *Id.* at ¶ 20. To use the tool, the organ information is first accessed by an authorized user—i.e., a transplant center employee, contractor, or other person who has permission to access the information—through

¹ In communications with UNOS leading up to this lawsuit, Buckeye used generic names for these services and uses these easier-to-understand titles to ensure clarity herein.

the OPTN systems website. The user accesses the website through an ordinary internet browser. After the user logs into the OPTN systems and pulls up the information in the user's browser, the tool scans and processes the content of the webpage (which is already visible to the user) to retrieve the data points that the user needs to evaluate the organ offer. *Id.* at ¶ 21.

The Rapid Organ Assessment Tool is essentially an automated “copy and paste” mechanism that excerpts and compiles pertinent information for the transplant personnel's review. The plug-in operates by quickly and accurately distilling the large volume of information contained on the webpage down to the data points required for transplant personnel to determine whether an organ offer is suitable for the potential recipient. *Id.* at ¶ 22. By using the tool to automate administrative labor that would otherwise require time-consuming manual review, the user is able to save substantial processing time in evaluating whether the organ is suitable. The use of the tool therefore directly decreases the transplant center's decision-making and response time in either accepting or declining the offer. *Id.* at ¶ 23.

In cases where the organ is not suitable, the Rapid Organ Assessment Tool is able to help transplant personnel rule out an offer within minutes, thus permitting the organ to be made available to another transplant center that may be able to make use of it. In cases where an offer passes the initial screening, the coordinator is able to effectively compile the necessary information to afford the decision-maker (i.e., the surgeon) maximum time to review the information and make the best decision for the patient. *Id.* at ¶ 24.

Because the tool automates the review and retrieval of pertinent information, it avoids mistakes due to human error that may occur in the manual review process. The tool increases accuracy because it eliminates the need for the user to either retype or manually copy and paste the data into new locations, both of which risk inadvertent errors. This automation reduces the

risk of a transplant center mistakenly identifying an unsuitable organ as acceptable, or vice versa—a devastating mistake that could potentially cost a patient’s life. For example, if a donor’s blood type is “AB” and a user manually copies this information as “A,” the organ may be transplanted into a recipient with A blood type—a potentially fatal error. Ackley Decl. ¶ 25.

The continued use of the Rapid Organ Assessment Tool is imperative to Buckeye’s transplant center clients. Buckeye assists transplant centers in assessing and processing over 20,000 organ offers per month. It is impossible for Buckeye or any transplant center Buckeye serves to assess and make timely decisions regarding as many organ offers as efficiently as they can at present without the assistance of Buckeye’s tool. *Id.* at ¶ 27. If Buckeye is unable to utilize the tool, evaluation times will be extended, causing longer allocation times and in some cases the inability of the transplant center to timely respond to an offer. These delays in evaluating an organ could result in worse patient outcomes and cause potentially transplantable organs to become unviable or otherwise unavailable. *Id.* at ¶ 27.

B. Operational Assessment Tool

The Operational Assessment Tool is also a browser tool that processes and compiles information for the transplant center’s use. The Operational Assessment Tool retrieves and compiles data on the outcomes of organs that had been previously declined by the transplant center, in order to identify instances where the declined organ had been successfully transplanted elsewhere. Ackley Decl. ¶ 29. The primary purpose of the Operational Assessment Tool is to enable transplant centers to analyze retrospective data for the purpose of improving their clinical practices and procedures. For example, if a large number of the transplant center’s declined organs were ultimately successfully transplanted elsewhere, that trend may indicate to a transplant center that it needs to re-evaluate its offer filter criteria and provide guidance to the transplant center on areas of improvement for their donor screening policies. *Id.* at ¶ 31. As with

the Rapid Organ Assessment Tool, the data captured by the Operational Assessment Tool for each of Buckeye's clients is information that is already available to that transplant center. The Operational Assessment Tool is accessed through the user's ordinary internet browser and compiles only information that the user is authorized to access on the OPTN systems. *Id.* at ¶ 32.

III. In March 2023, the Federal Government Announced that UNOS' Thirty-Year Monopoly May End

UNOS has been roundly criticized for its ineptitude in managing the organ transplant system in the United States, a task over which it has had a monopoly since the 1980s. *See* Compl. ¶¶ 4-6. In March, the U.S. Health Resources and Services Administration ("HRSA") announced a modernization initiative, including a plan to solicit bids to potentially replace UNOS as the monopolist operator of OPTN. *See id.* at ¶ 52. UNOS has trumpeted its own perceived abilities and suggested that it would bid to continue as the contractor and suggested that it will bid for the next contract. *See id.* at ¶ 54. UNOS' desire to retain its monopolist role creates an incentive for UNOS to undermine the public perception and operational abilities of any entity that might compete with UNOS in the upcoming contract bidding process. UNOS also has a unique ability, as the incumbent operator of the system, to abuse its position in furtherance of its own competitive goals.

IV. UNOS is Targeting Its Potential Competitor Buckeye

Over the last two months, UNOS has been targeting its potential competitor Buckeye for scrutiny in how Buckeye uses the OPTN. UNOS' aggressive treatment of Buckeye began after business hours on Friday, May 5, when UNOS sent a cease-and-desist letter to Buckeye inquiring about what UNOS characterized as potential privacy incident and demanding a response by the following Monday. Declaration of Ross D'Emanuele ("D'Emanuele Decl."), ¶ 2. Buckeye timely responded and provided the assurances requested and pledged its full

cooperation with providing whatever additional information UNOS and OPTN might request. *Id.* at ¶ 3, Ex. B.

The same day that Buckeye responded—and before UNOS or OPTN made any additional requests of Buckeye—UNOS told Buckeye that UNOS planned to inform Buckeye’s customers of UNOS’ view of the situation. *Id.* at ¶ 4. Buckeye wrote to UNOS on May 9 and objected to UNOS or OPTN “raising unfounded and speculative allegations against Buckeye” in any communications with Buckeye’s customers. *Id.* at ¶ 5. In calls with Buckeye’s counsel on May 9, UNOS confirmed its intent to send Buckeye additional requests for information but planned to communicate with Buckeye’s customers imminently before requesting any additional information from Buckeye. *Id.* at ¶ 6.

Indeed, UNOS did just that, transmitting an email in the evening of May 9 to Buckeye’s customers, with the subject line “Important: Update to users of Buckeye Transplant Services,” which read, in relevant part:

We wanted to let you know we are in an ongoing investigation of a potential privacy incident. We are working collaboratively with the contractor to identify the scope of the potential incident. While we continue our investigation, we have taken immediate steps to mitigate any risk to the OPTN Computer System and OPTN data.

As a best practice, you should review your current privacy and security arrangements with any vendors to whom you provide access to OPTN data to confirm that they have appropriate privacy and security controls.

Ackley Decl. ¶ 33, Ex. A. Just as Buckeye feared, Buckeye’s clients reacted to UNOS’ email with alarm. Within three hours of the email’s transmission, the director of clinical services for a prominent transplant center on the West Coast emailed Buckeye’s president, asking “can you let us know what this is regarding and if there is any action required from our end?” *Id.* at ¶¶ 33-34, Ex. A. By the next morning, May 10, Buckeye had received communications from eight other clients similarly expressing their alarm. For example, around 7:30 a.m. EDT on May 10, 2023,

the director of transplant operations at a prominent East Coast transplant center emailed Buckeye's president to inquire about the UNOS email, stating that the transplant center was "very alert to breaches with IT and concerns for patient information," and further requesting that Buckeye validate that a list of 41 individuals were properly authorized to access the transplant center's data for its heart and kidney transplant programs. *Id.* at ¶ 35. Buckeye's senior personnel spent the next several days speaking with senior administrators and physicians from ten different transplant centers to explain the situation and address their concerns following the UNOS email. *Id.* at ¶ 36.

Buckeye's clients have had more than questions: over the past two months, they have decreased their usage of Buckeye's tools, causing hundreds of thousands of dollars in lost billings and stalled contracts since the UNOS email, and several of Buckeye's clients have initiated termination of its services. *Id.* at ¶ 37. In addition, the UNOS email caused internal concern and uncertainty among Buckeye's personnel, who feared that UNOS' position had put their jobs in jeopardy. Additionally, Buckeye's attempts to respond to UNOS' demands by modifying its operations over the past two months have resulted in a significantly increased burden on its personnel. As a result, multiple Buckeye employees have quit in response to the changing demands, uncertainty, and increased workload. Buckeye will spend tens of thousands of dollars in recruiting and training new employees to fill these roles. *Id.* at ¶ 38

V. Despite UNOS' Anti-Competitive Targeting, Buckeye Cooperated with UNOS' Exhaustive Investigation of Buckeye

Hours after the email to Buckeye's customers on May 9, Livingston transmitted a three-page (single spaced) document entitled "OPTN Questions for Buckeye Transplant Services" to Buckeye's counsel. The document was a list of 35 questions, relating to Buckeye's privacy and security controls for protecting OPTN data. D'Emanuele Decl. ¶ 7, Ex. C. This was the first of

many requests that would continue in the weeks that followed. *See id.* at ¶¶ 7-18. Buckeye provided UNOS with documents, answered detailed technical questions, and held two live demos in which it showed how it uses its technology for UNOS personnel. *See id.*

The second demonstration was held on May 31, 2023 and Buckeye answered numerous questions about its operations and its privacy and security framework. UNOS indicated that it would provide any other final questions it may have to conclude its investigation. *Id.* at ¶ 18. After hearing nothing from UNOS for over a week, Buckeye counsel provided correspondence to UNOS/OPTN counsel on June 8, 2023 stating Buckeye’s position that the UNOS inquiry should end. *Id.* at ¶ 19, Ex D. In addition, Buckeye stated that: (1) the same UNOS leadership that sent the communication of May 9, 2023 to Buckeye customers should send another communication to the same set of Buckeye customers indicating that OPTN has ended its investigation and found no privacy or security breach, no compromise of the OPTN Computer System or OPTN data, and no material privacy or security issues with regard to the activities of the contractor being reviewed; (2) UNOS should confirm that Buckeye may continue to utilize the “plug-in tool” that was demonstrated to UNOS and HRSA personnel on May 24, 2023; and (3) UNOS should confirm that Buckeye may resume use of what we have referred to as the “automated script” that Buckeye has halted using in response to the initial demands of UNOS in early March. *Id.* at ¶¶ 19-20, Ex D. Buckeye expressed willingness to agree to volume limitations or other reasonable conditions on the use of this tool upon UNOS’ request. *Id.*

Instead of complying with Buckeye’s requests or engaging further, UNOS sent another cease and desist letter to Buckeye on June 21 alleging that Buckeye is violating the 2018 UNOS Terms of Use and the OPTN Policies in two respects. D’Emanuele Decl. ¶ 22, Ex. E. First, the June 21 letter alleges that Buckeye’s Rapid Organ Assessment Tool violates section 6(c) of the

terms, which states: “You may not ... use data mining, robots, or other data gathering devices on or through UNOS Systems, unless specifically allowed by these Terms,” as well as section 7 of the terms, which states: “You may not use, copy, store, reproduce, transmit, distribute, display, modify, alter, license, sublicense, or commercially exploit UNOS Systems or any contents, information, data or materials provided through UNOS Systems in any manner not expressly permitted by these Terms of Use.” *Id.* Second, the June 21 letter alleges that Buckeye’s Operational Assessment Tool violates section 3.1.A of the OPTN Policies, entitled “Non-member Access,” and which states “Members may not use the match system for non-members or allow non-members access to the match system unless all of the following requirements are met: ... 1. The non-member is assisting the member with facilitating organ transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN.” The letter asserted that “Because after-the-fact reviews of information falls into none of the categories above, it is, inherently, impermissible.” *Id.* The June 21 letter continued: “For the avoidance of doubt, despite the availability of the OPTN data at issue, Buckeye is not authorized to access it or to use such OPTN data in any way. Instead, for any information other than in-the-moment information necessary for the evaluation and placement of organs, all OPTN data and information must be obtained using a specific data request to the OPTN.” The letter further stated: “We hereby demand that Buckeye cease any use of UNOS Systems that violate the UNOS Systems Terms of Use that would constitute the use of any data other than that which relates, narrowly, to contemporaneous facilitation, placement, and reporting to the OPTN.” *Id.*

The June 21 letter demanded that Buckeye “certify destruction of all identifiable OPTN data, including all electronic copies of data wherever stored, to include on all Buckeye employee devices.” *Id.* Buckeye counsel responded the next day asking UNOS to reconsider the manner it

was seeking to enforce its interpretation of the terms and policies, and, for purposes of ensuring continued patient care, asking UNOS to engage in good faith discussions to develop conditions under which Buckeye could continue to operate by agreement. *Id.* at ¶ 23, Ex. F.

VI. UNOS’ Interpretation of Its Terms of Use Is Incorrect, and Until June 30, 2023, Was Applied Only to Buckeye

In Buckeye’s counsel’s letter transmitted June 22, Buckeye articulated its position as to why UNOS’ interpretation of its terms of use was incorrect. Buckeye explained that UNOS’ position rested on—at best—an unpromulgated new interpretation of its Terms of Use being applied solely to Buckeye. D’Emanuele Decl. ¶ 23, Ex. F. Buckeye requested that if UNOS’ new interpretations were to apply to all transplant centers, transplant service providers, OPOs, and all other OPTN members, then UNOS should apply and enforce these interpretations of the Terms of Use fairly, consistently, and appropriately. UNOS should first promulgate public guidance setting forth these interpretations. UNOS should then set a deadline for the entire transplant community to come into compliance. This would treat all OPTN members equally and give the entire transplant community consistent guidance and a consistent timeframe in which to modify current practices to comply with UNOS’ interpretation of the Terms of Use. Buckeye pledged that it would certainly comply if UNOS took this approach. *Id.*

UNOS responded through counsel on Wednesday, June 28 via email rejecting any further discussion with Buckeye and stating that Buckeye must follow UNOS’ demands no later than July 5 or its users’ account access will be terminated. *Id.* at ¶ 24, Ex. G. UNOS’ counsel stated: “please note that the last day that Buckeye will be able to use the clinical tool is July 5, 2023 [and] we expect to receive the Declaration of Data Destruction form to be returned promptly, but in no case later than July 5, 2023.” *Id.*

VII. UNOS Finally Announced Its New Interpretation of its Terms of Use to a Broader Audience—on June 30, 2023.

On June 30, 2023, OPTN emailed its members with the subject line “Important reminder for review of vendor security and data privacy.” Ackley Decl. ¶ 39, Ex. B. The email stated: “The use of unauthorized automated tools (e.g., data mining, robots, and other data gathering devices commonly referred to as screen scraping) to extract OPTN data directly from the OPTN computer system is not permitted.” *Id.* A portion of the foregoing sentence is drawn from section 6(c) of the UNOS Terms of Use, which reads: “You may not: ... use data mining, robots, or other data gathering devices on or through UNOS Systems, unless specifically allowed by these Terms.” The phrase “commonly referred to as screen scraping” does not appear in the UNOS Terms of Use; rather, this phrase apparently reflects UNOS new interpretation of its Terms of Use. *Id.*; *see* D’Emanuele Decl. ¶ 25, Ex. H (UNOS Terms of Use).

VIII. UNOS Offers Tools with the Very Same Features It Now Claims Buckeye Cannot Offer, But Buckeye’s Clients Prefer Its Operational Assessment Tool to Other Available Alternatives

UNOS went so far as to highlight its own competing tool in the June 30 email, writing: “If you need data to assess the performance of your institution, there are tools within Secure Enterprise to request such data, as well as a number of helpful reports.” Ackley Decl. ¶ 39, Ex. B. Far from believing that the tools Buckeye offers its customers are not consistent with a well-functioning transplant system, UNOS itself offers (or attempts to offer) tools with features similar to Buckeye’s Operational Assessment Tool. *See* Compl. ¶¶ 118-124. For example, UNOS offers what it calls the “CARE tool,” which UNOS describes as an “interactive tool allows transplant centers to review their own organ acceptance rates for specific types of donors, along with transplant specific and aggregate outcomes information on the organs they refused that were transplanted elsewhere.” *Id.* at ¶ 119. Among other data points, the UNOS Care tool displays

specific donor IDs and the details of organs that became available from those donors. This appears identical to the dataset that UNOS claims its terms preclude Buckeye from directly providing to transplant centers about their patients. *Id.* at ¶ 120. Other UNOS webpages confirm that it will provide “Donor, candidate, and recipient-specific records” and “Post-transplant follow-up data” through its data portal. *Id.*

Buckeye’s transplant center clients prefer that Buckeye provide them with data regarding the centers’ past decisions to accept or not accept organs for transplant. Ackley Decl. ¶ 40. In 2019, one of Buckeye’s clients in a mid-Atlantic state wrote in response to receiving data from Buckeye that “This is excellent information, much better than our previous vendor.” *Id.* at ¶ 41. Buckeye’s clients use its services to comply with CMS demands. One New England client wrote in July 2021: “Is it possible to also get the heart organ offer reports? I am not sure who they are being sent to since [employee] has retired as well as I am complying everything for our impending CMS transplant re-certification survey.” *Id.* at ¶ 42. Another of Buckeye’s clients—an academic teaching hospital on the West Coast—emailed Buckeye in January 2023 seeking Buckeye’s assistance gathering data to “assist me with a UNOS/OPTN project I am working on.” *Id.* at ¶ 43. The client continued: “We are working on how to increase DCD transplants and improve workflows.” *Id.* The client requested “# of DCD donors for 2020, 2021 and 2022,” “# of DCD donors that were DRY RUNS for each year,” and “# of DCD donors that were OCS cases for each year.” *Id.* The client could request some of this data from UNOS if it wanted to, but UNOS does not record certain of the transplant center’s decision-making data; the client thus chose to use Buckeye’s services instead. *Id.*

Even when Buckeye experienced some delays in providing data during the summer of 2022 because of a high volume of requests, one of its clients confirmed that it wished for

Buckeye to press forward and continue providing services, writing: “Like [] the other centers, we are desperate to have the report. The report is being asked [for] by our physicians pretty frequently.” *Id.* at ¶ 44. Buckeye’s clients use Buckeye’s services to improve patient care. One of Buckeye’s mid-Atlantic transplant center clients wrote to Buckeye in November of 2022 about a data request and tied the request to that purpose: “We finally started to have an increase in organ offer(s) and acceptance rate. I do not want to lose momentum. We are still behind in our transplant volume for this calendar year and need to catch up.” *Id.* at ¶ 45

Another client, in the Southeastern U.S., tied the need for data from Buckeye to the client’s efforts to provide UNOS with information it requires, writing in April 2023: “Good morning, I was wondering if I can get list of all donor offers (Donor ID and Match ID) from January 2022 through May 2022. This is preparation for the upcoming UNOS site visit. One of our patient’s record is being reviewed.” *Id.* at ¶ 46

Just last month, one of Buckeye’s clients responded to a Buckeye data report with effusive praise, writing:

This is perfect!!!-and I am so very appreciative that you pulled this together for me. I can’t thank you enough.

This is a lifesaver for tomorrow evening’s presentation.

I have been asked to do monthly organ offer review meetings with our transplant physicians and the executive physician team for the entire cardiac division of [the center] and without reports, I have to do all of the extrapolation manually.

Thanks again for pulling this together!

Id. at ¶ 47. Buckeye’s clients clearly prefer Buckeye’s services to those of UNOS. Only through improper anti-competitive means can UNOS force Buckeye’s clients to choose UNOS’ data delivery services. UNOS’ behavior described above appears calculated to do exactly that. *Id.* at ¶ 48.

ARGUMENT

Fed. R. Civ. P. 65 authorizes the issuance of temporary restraining orders and preliminary injunctions. The standard for granting a TRO is the same as that for granting a preliminary injunction. *See Moore v. Kempthorne*, 464 F. Supp. 2d 519, 525 (E.D. Va. 2006). “Prohibitory preliminary injunctions aim to maintain the status quo and prevent irreparable harm while a lawsuit remains pending.” *Pashby v. Delia*, 709 F.3d 307, 319 (4th Cir. 2013). A TRO or preliminary injunction should issue if the movant establishes that (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of injunctive relief; (3) the balance of the equities tips in its favor; and (4) an injunction would be in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008); *Centro Tepeyac v. Montgomery Cty.*, 722 F.3d 184, 188 (4th Cir. 2013) (en banc). Each of these elements is satisfied here.

I. Buckeye Is Likely to Succeed on the Merits of its Claims

To demonstrate likelihood of success on the merits, a plaintiff seeking “to preserve the status quo” via a prohibitory injunction must make “a ‘clear showing’ that they are likely to succeed at trial.” *Pashby*, 709 F.3d at 320, 321. They do not need to show “a certainty of success.” *Id.* at 321. In cases involving multiple claims, a plaintiff need only demonstrate that they are likely to succeed on at least one of their claims. *E.g., Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc.*, 193 F. Supp. 3d 556, 567 (E.D. Va. 2016) (quoting *W. Indus.-N., LLC v. Lessard*, No. 1:12-cv-177, 2012 WL 966028, at *2 (E.D. Va. Mar. 21, 2012)). Buckeye asserts claims for declaratory judgment, tortious interference, breach of contract, and attempted monopolization under § 2 of the Sherman Act. Buckeye is likely to succeed on each cause of action asserted in its Complaint.

A. Declaratory Judgment

Pursuant to 28 U.S.C. § 2201 *et seq.*, a federal district court may “declare the rights and other legal relations of any interested party” so long as there exists (1) “an ‘actual controversy’ between the parties ‘of sufficient immediacy and reality to warrant issuance of a declaratory judgment;’” (2) the court has an independent basis for jurisdiction over the parties, such as diversity jurisdiction; and (3) the court does not “abuse its discretion.” 28 U.S.C. § 2201(a); *Volvo Constr. Equip. N. Am., Inc. v. CLM Equip. Co.*, 386 F.3d 581, 592 (4th Cir. 2004) (citations omitted); *see also In re Capital One Consumer Data Sec. Breach Litig.*, 488 F. Supp. 3d 374, 414 (E.D. Va. 2020) (a stated dispute must be capable of “conclusive relief” and non-hypothetical). “[I]t is well established in the Fourth Circuit that a declaratory judgment is appropriate ‘when the judgment will serve a useful purpose in clarifying and settling the legal relations in issue, and . . . when it will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding.’” *Bartley v. Merrifield Town Ctr. Ltd. P’ship*, 580 F. Supp. 2d 495, 501 (E.D. Va. 2008) (quoting *Centennial Life Ins. Co. v. Poston*, 88 F.3d 255, 256 (4th Cir. 1996)). A district court is given “great latitude” in deciding to exercise its discretion, so long as the first two factors are met. *United Capitol Ins. Co. v. Kapiloff*, 155 F.3d 488, 493 (4th Cir. 1998).

1. UNOS’ Interpretation of Its Terms of Use is Incorrect

UNOS’ June 21 letter alleges that Buckeye’s Rapid Organ Assessment Tool violates section 6(c) of the 2018 UNOS Terms of Use, which states: “You may not . . . use data mining, robots, or other data gathering devices on or through UNOS Systems, unless specifically allowed by these Terms,” as well as section 7 of the terms, which states: “You may not use, copy, store, reproduce, transmit, distribute, display, modify, alter, license, sublicense, or commercially exploit UNOS Systems or any contents, information, data or materials provided through UNOS

Systems in any manner not expressly permitted by these Terms of Use.” D’Emanuele Decl. ¶ 22, Ex. E; *see also id.* at ¶ 25, Ex. H (the current UNOS Terms of Use).

UNOS’ position rests on—at best—an unpromulgated new interpretation of its Terms of Use being applied solely to Buckeye. The initial paragraph of the Terms of Use states that “UNOS provides access to UNOS Systems and other software and data to approved transplant professionals in order to match organ donors with recipients as well as for certain quality assurance and improvement activities related to organ transplantation.” *Id.* at ¶ 25, Ex. H. Buckeye accesses and uses the UNOS system and data solely for those allowed and permitted purposes. *See generally* Ackley Decl. (describing Buckeye’s use of OPTN data and operation of its products).

UNOS’ June 30 email to OPTN members highlights how UNOS’ interpretation is new. *See* Ackley Decl. ¶ 39, Ex. B (the June 30 email). The email states: “The use of unauthorized automated tools (e.g., data mining, robots, and other data gathering devices commonly referred to as screen scraping) to extract OPTN data directly from the OPTN computer system is not permitted.” *Id.* A portion of the foregoing sentence is drawn from section 6(c) of the terms, which reads: “You may not: ... use data mining, robots, or other data gathering devices on or through UNOS Systems, unless specifically allowed by these Terms.” Compare *id.* with D’Emanuele Decl. ¶ 25, Ex. H § 6 (the full “Acceptable Use” section from the UNOS Terms of Use). The phrase “commonly referred to as screen scraping” does not appear in the UNOS Terms of Use; rather, this phrase apparently reflects UNOS new interpretation of its Terms of Use. *See* D’Emanuele Decl. ¶ 25, Ex. H (the current UNOS Terms of Use, with no mention of “screen scraping”).

UNOS' June 30, 2023 email, which adds language to the UNOS Terms of Use, confirms that—as written—those terms do not explicitly prohibit what UNOS has termed “screen scraping.” A ban on “screen scraping” is not implied by the language actually in the Terms of Use—“data mining, robots, or other data gathering devices on or through UNOS Systems”—because unlike “data mining,” “robots” or other devices that operate “on or through UNOS Systems,” so-called “screen scraping” has no impact on the technological workload the UNOS Systems must bear, and is deployed solely on the user’s internal web browser.

Buckeye’s Rapid Organ Assessment Tool illustrates this point. The tool is a plugin that operates on the ordinary internet browser utilized by Buckeye personnel as authorized users of the OPTN. Ackley Decl. ¶¶ 20-21. The tool copies and pastes data that is visible to the users on their internet browser, and thus speeds up the otherwise manual process of copying essential information for the transplant center’s use. *Id.* at ¶ 22. For that reason, Buckeye’s tool is not even properly characterized as “screen scraping,” a pejorative term seemingly intended to sound nefarious. Buckeye’s tool merely facilitates a user’s rapid capture of data the user is authorized to see and must communicate to others on the transplant team. *See id.* at ¶¶ 20-26 (describing the structure, operation, and use of the Rapid Organ Assessment Tool). Buckeye’s tool does not burden UNOS Systems because the tool merely copies data that the user has already requested be sent to the user’s internet browser. *Id.* This makes the tool unlike “data mining” or “robots” because the tool does not operate “on or through UNOS Systems.” D’Emanuele Decl. ¶ 25, Ex. H (UNOS Terms of Service). UNOS is thus attempting to change the nature of that prohibition from a prohibition on automated tools based on where the tools are deployed, into a prohibition based on a certain purpose (i.e., to extract OPTN data from the OPTN computer system regardless of on what or whose systems the tool is deployed).

2. UNOS' Interpretation of the OPTN Policies Is Also Incorrect

UNOS' June 21 letter also alleges that Buckeye's Operational Assessment Tool² violates section 3.1.A of the OPTN Policies, entitled "Non-member Access," and which states "Members may not use the match system for non-members or allow non-members access to the match system unless all of the following requirements are met: ... 1. The non-member is assisting the member with facilitating organ transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN." D'Emanuele Decl. ¶ 22, Ex. E; *see also id.* at ¶ 26, Ex. I (current OPTN Policy 3.1 "Access to Computer Systems"). The letter asserted that "Because after-the-fact reviews of information falls into none of the categories above, it is, inherently, impermissible." *Id.* at ¶ 22, Ex. E. The letter continued: "For the avoidance of doubt, despite the availability of the OPTN data at issue, Buckeye is not authorized to access it or to use such OPTN data in any way. Instead, for any information other than in-the-moment information necessary for the evaluation and placement of organs, all OPTN data and information must be obtained using a specific data request to the OPTN." *Id.*

UNOS' interpretation is incorrect for at least two reasons. First, UNOS cited section 3.1.A of the OPTN Policies, entitled "Non-member Access," and which UNOS claims makes "after-the-fact reviews of information ... inherently, impermissible." *Id.* But Buckeye is not a "non-member" of OPTN, Buckeye is a business member, rendering section 3.1.A facially inapplicable. Second, Buckeye's Operational Assessment Tool merely enables more accurate and efficient use of data that Buckeye's transplant center customers already have access to. *See* Ackley Decl. ¶¶ 29-32 (describing the structure, operation, and use of the tool). Contrary to

² Buckeye does not seek a temporary restraining order as to the Operational Assessment Tool, so the Court likely does not need to address this part of the dispute at this time.

UNOS’ attempt to prohibit any user from using any data for purposes other than “narrowly” for “contemporaneous facilitation, placement, and reporting to OPTN,” review of post-transplant data is a critical (and nearly universal) part of the transplant process at every transplant center, and is absolutely essential to the facilitation of organ transplants. It is undisputed that UNOS makes so-called “after-the-fact” information available to transplant centers. *See* Compl. ¶ 13. There is no reason for UNOS to do that if the transplant centers—and their agents, such as Buckeye—are never allowed to use the data.

B. Tortious Interference

To succeed on a claim for tortious interference in Virginia, a plaintiff must demonstrate “(1) the existence of a valid contractual relationship or business expectancy; (2) knowledge of the relationship or expectancy on the part of the interferor; (3) intentional interference inducing or causing a breach or termination of the relationship or expectancy; and (4) resultant damage to the party whose relationship or expectancy has been disrupted.” *Dunlap v. Cottman Transmission Sys., LLC*, 287 Va. 207, 216, 754 S.E.2d 313, 318 (2014). Tortious interference in at will contracts or business expectancies additionally requires that the defendant used “improper methods,” *id.*, including “baseless litigation, fraud, deceit, duress, undue influence, unfair competition, or the breach of a fiduciary duty.” *Carfax, Inc. v. Red Mt. Techs.*, 119 F. Supp. 3d 404, 415-16 (E.D. Va. 2015) (citing *Duggin v. Adams*, 234 Va. 221, 227, 360 S.E.2d 832, 836 (1987)). Improper methods also encompasses “less egregious . . . violations of ‘an established standard of a trade or profession . . . , unethical conduct . . . , sharp dealing, overreaching, or unfair competition’” *Commerce Funding Corp. v. Worldwide Sec. Servs. Corp.*, 249 F.3d 204, 214 (4th Cir. 2001) (citing *Duggin*, 360 S.E.2d at 837).

Buckeye is likely to succeed in its tortious interference claim. Buckeye has valid contractual relationships with its client transplant centers for Buckeye’s provision of various

services to the transplant centers, including technology-assisted organ offer screening services and data reporting. *See* Ackley Decl. ¶¶ 3-17 (describing Buckeye’s relationships and services). Buckeye has a valid business expectancy that its clients will continue to use Buckeye’s services consistent with their historical usage. UNOS is well aware of Buckeye’s contractual relationships, including because Buckeye specifically informed UNOS that UNOS’ planned course of conduct would harm those relationships and because Buckeye provided UNOS with redacted examples of Buckeye’s contracts with its customers. *See* D’Emanuele Decl. ¶¶ 3-19 (describing efforts of Buckeye’s counsel to communicate with UNOS).

UNOS intentionally interfered with Buckeye’s contractual relationships with its customers and business expectancy that those customers will continue to use Buckeye’s services, in at least two ways. First, UNOS emailed “users of Buckeye Transplant Services” on March 9, 2023, announcing “an ongoing investigation of a potential privacy incident” when, in truth, UNOS had not even transmitted the questions about the supposed “privacy incident” that it wanted Buckeye to answer when it emailed Buckeye’s customers. UNOS also encouraged Buckeye’s customers to “review your current privacy and security arrangements with any vendors to whom you provide access to OPTN data,” thus instructing Buckeye’s customers that the “privacy incident” should cause the customers to “review” their business relationship with Buckeye. Further, UNOS has ignored Buckeye’s requests that UNOS send a corrective communication to Buckeye’s customers confirming that UNOS’ investigation confirmed that there was no “privacy incident” in the first place. Second, UNOS has purported to use its role as enforcer of the 2018 UNOS Terms of Use and the OPTN Policies to force Buckeye to deactivate its tools and delete transplant center data. The circumstances under which UNOS has issued its demands to Buckeye described herein provide strong evidence that UNOS’ purpose is not a good

faith enforcement of applicable rules, but rather to hobble potential competition UNOS will face in the upcoming bid process that will determine whether UNOS retains its thirty-six year monopoly on running the U.S. organ transplant system.

UNOS' intentional interference with Buckeye's contracts and business expectancy has induced or caused some of Buckeye's customers to breach or terminate their relationships and damages Buckeye's business expectancy. Buckeye has sustained monetary damages as a result of UNOS' interference. UNOS has interfered with Buckeye's business expectancy employing improper methods, including threats, intimidation, undue influence, unfair competition, violating established standards of the parties' trade and profession, sharp dealing, and overreaching.

C. Breach of Contract

To succeed on a claim for breach of contract in Virginia, a plaintiff must demonstrate that the defendant violated or breached a "legally enforceable obligation" between the parties, causing injury to the plaintiff. *E.g., Doctors Co. v. Women's Healthcare Assocs., Inc.*, 285 Va. 566, 578 (Va. 2013); *Knox Energy, LLC v. Gasco Drilling, Inc.*, 738 Fed. Appx. 122, 124 (4th Cir. 2018). A breach is material when it "deprive[s] the injured party of the benefit that the party justifiably expected from the exchange." *RW Power Partners, L.P. v. Va. Elec. Power Co.*, 899 F. Supp. 1490, 1496 (E.D. Va. 1995) (quotation omitted).

Buckeye is likely to succeed on its breach of contract claim. Having accepted Buckeye's request to become a business member of UNOS and permitted Buckeye to perform services for its transplant center clients, UNOS accepted a legally enforceable obligation to Buckeye to apply the 2018 UNOS Terms of Use and OPTN Policies in a legally correct manner. UNOS has breached its obligation to Buckeye, including by applying the 2018 Terms of Use and OPTN Policies to Buckeye via unsupportable interpretations of those documents, singling out Buckeye for arbitrary treatment not consistent with prevailing standards in the industry, and targeting

Buckeye to squash competition. Buckeye was and is damaged by UNOS' breach of obligation insofar as Buckeye's customer relationships have been harmed by UNOS' inaccurate public statements about Buckeye, UNOS' insistence that Buckeye exhaustively share information about its services with UNOS for UNOS' improper purpose of damaging Buckeye. Further, Buckeye will be damaged if UNOS compels Buckeye to either accede to UNOS' incorrect interpretation of the 2018 UNOS Terms of Use and OPTN Policies by refraining from providing lifesaving services for Buckeye's customers and irreversibly deleting data gathered for the transplant centers that Buckeye serves.

D. Attempted Monopolization Under § 2 of the Sherman Act

A plaintiff must demonstrate that a defendant (1) possessed the “specific intent to monopolize the relevant market;” (2) undertook “predatory or anticompetitive acts in furtherance;” and (3) had “a dangerous probability of success.” *E.I. Dupont De Nemours & Co. v. Kolon Indus.*, 688 F. Supp. 2d 443, 456 (E.D. Va. 2009) (citing *M & M Med. Supplies & Serv., Inc. v. Pleasant Valley Hosp., Inc.*, 981 F.2d 160, 166 (4th Cir. 1992)). The defendant must also have engaged in “conduct . . . that is unreasonably exclusionary or predatory,” or otherwise “lack[ing] . . . a legitimate business justification.” *Id.* (citation omitted). Further, a plaintiff must sufficiently allege an “injury caused by damage to the competitive process” to sustain an antitrust claim—that they were “excluded from participation in a particular market” by the defendant, “and the result was a decrease in competition in that market.” *E.I. DuPont de Nemours & Co.*, 688 F. Supp. 2d at 460 (quoting *Thompson Everett, Inc. v. National Cable Adver.*, 57 F.3d 1317, 1325 (4th Cir. 1995)).

Buckeye is likely to succeed on its attempted monopolization claim. Buckeye and UNOS are competitors in the market for providing transplant centers in the U.S. with data regarding the centers' past decisions to accept or not accept organs for transplant. This data is valuable to

transplant centers because they use it for quality assurance and quality improvement purposes, as well as to comply with regulatory requirements imposed by CMS. Not only do Buckeye and UNOS compete insofar as each can provide transplant centers with the data that they need, Buckeye and UNOS compete in how the information is presented because the presentation of data in an efficient and useful manner can save transplant centers time and resources and is thus valuable to them.

UNOS is using anticompetitive conduct to attempt to monopolize this market, including by issuing directives to Buckeye to stop providing its services to transplant centers based on legally erroneous interpretations of the 2018 UNOS Terms of Use and the OPTN Policies. UNOS is also targeting Buckeye, such as by communicating supposed concerns about a “privacy incident” specifically to Buckeye’s customers and then ignoring Buckeye’s request for a corrective communication after UNOS’ privacy concerns were resolved. UNOS has the specific intent to monopolize because it continues to promote its own ability to offer the services it demands that Buckeye refrain from offering with no technical, privacy, or other reason why only UNOS can offer these services and Buckeye cannot. UNOS has not and cannot offer any rationale for reserving for itself the right to offer these services while denying that right to Buckeye other than UNOS’ desire to monopolize the market. UNOS has a dangerous probability of succeeding in its attempt to monopolize the U.S. market for providing transplant centers with data regarding the centers’ past decisions to accept or not accept organs for transplant because UNOS is using coercive methods to force Buckeye to comply with UNOS’ demands, including the customer communication discussed above and UNOS’ threat to remove Buckeye’s access to the OPTN on July 5, 2023 if Buckeye does not accede to UNOS’ demands and not providing for

any opportunity for a neutral third-party to determine whether UNOS' interpretation of its Terms of Use and OPTN Policies is correct and consistent with prevailing industry practices.

UNOS' attempts to exclude Buckeye from the market will harm Buckeye, competition, and consumers of the services UNOS and Buckeye offer because absent Buckeye's competition, there will be no market pressure on UNOS to charge lower prices or deliver a higher quality product. This harm to the transplant centers Buckeye serves will in turn harm patients in need of organ transplants because the centers' ability to improve their practices and approaches depends on the quality assurance and improvement practices informed by the data Buckeye provides. Buckeye is losing customers, and as such, market share, it otherwise would have won by virtue of its investment in, and adoption of, innovative tools for providing transplant centers with data regarding the centers' past decisions to accept or not accept organs for transplant.

II. Buckeye Will Suffer Irreparable Harm Absent a TRO and Injunction

Irreparable harm must be "actual and imminent," and generally occurs in circumstances where monetary damages would provide an inadequate remedy or would be difficult to quantify. *Update, Inc. v. Samilow*, 311 F. Supp. 3d 784, 796 (E.D. Va. 2018) (citing *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994); *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991)). "[T]he Fourth Circuit has repeatedly recognized that '[t]he threat of a permanent loss of customers and the potential loss of goodwill . . . support a finding of irreparable harm.'" *Variable Annuity Life Ins. Co. v. Coreth*, 535 F. Supp. 3d 488, 517 (E.D. Va. 2021).

Buckeye began experiencing monetary and reputational harm as soon as UNOS emailed Buckeye's customers on May 9 insinuating that Buckeye was not safeguarding patient data and encouraging those customers to reexamine their relationship with Buckeye. Within hours, Buckeye received the first of many emails from customers reacting with alarm and asking for

assurances about Buckeye's privacy compliance. Buckeye's senior personnel have devoted significant energy to assuaging those concerns, but Buckeye's customers have decreased their usage of Buckeye's tools, causing hundreds of thousands of dollars in lost billings and stalled contracts since the UNOS email, and several of Buckeye's clients have initiated termination of its services. UNOS' conduct has also caused internal concern and uncertainty, leading to increased burden on Buckeye personnel—some of whom have quit their jobs.

More pressing, if UNOS succeeds in its demand that Buckeye stop using the Rapid Organ Assessment Tool, Buckeye's ability to serve its transplant center customers will be severely impeded, and those centers' ability to evaluate organs for transplant will be impeded. Assisting customers with expediting their accurate analysis of organ data goes to the core of Buckeye's service. Hobbling these activities will irreparably harm Buckeye. So too will mandating that Buckeye destroy years of data gathered for its customers. Buckeye accessed the data at issue on behalf of transplant centers as authorized by those centers and UNOS. Buckeye's customers routinely request the data and praise Buckeye's responsiveness and ability to provide the data the centers need to improve their patient care and comply with demands from CMS and UNOS. Requiring Buckeye to irreversibly destroy this data also strikes at the core of Buckeye's important service to its clients and would amount to irreparable harm.

III. The Balance of Equities Weigh in Favor of a TRO and Injunction

Balancing the equities consists of “balanc[ing] the competing claims of injury and . . . the effect on each party” should the court issue or decline to issue injunctive relief. *Winter*, 555 U.S. at 24. In sum, the court must “assess[] the harms facing both parties.” *E.I. Dupont De Nemours & Co. v. Kolon Indus., Inc.*, 894 F. Supp. 2d 691, 708 (E.D. Va. 2012). There will be no harm to UNOS if the Court grants Buckeye's motion. All Buckeye seeks is the right to use the same tools to provide the same services to its transplant center customers on Thursday, July 6 that it is

providing today. The only “harm” to UNOS should an injunction issue is precluding UNOS from arbitrarily applying its new interpretation of its terms of use and policies by hobbling Buckeye’s services and forcing Buckeye to irreversibly delete data before a neutral third-party has determined if UNOS’ interpretation is correct.³

IV. Injunctive Relief is in the Public Interest

“Courts . . . should pay particular regard for the public consequences” of injunctive relief, *Winter*, 555 U.S. at 24—that is, “whether . . . the injunction is in the public interest or will not adversely affect the public interest.” *Steves & Sons, Inc. v. Jeld-Wen, Inc.*, 612 F. Supp. 3d 563, 598 (E.D. Va. 2020) (citing *League of Women Voters v. North Carolina*, 769 F.3d 224, 236 (4th Cir. 2014)). The public interest’s relative importance may be magnified where the health and safety of individuals or the public is directly implicated. *See Belle Garden Estate, LLC v. Northam*, Civil Action No. 7:21cv00135, 2021 U.S. Dist. LEXIS 57609, at *22 (W.D. Va. Mar. 26, 2021) (under the public interest factor, the risk that more people would die outweighed one party’s monetary concerns); *see also Pashby*, 709 F.3d at 331 (“[T]he public interest in this case lies with safeguarding public health rather than with assuaging . . . budgetary woes”); *New York v. U.S. Dep’t of Homeland Sec.*, 969 F.3d 42, 87 (2d Cir. 2020) (public interest favors a preliminary injunction where an agency Rule “will likely result in ‘[w]orse health outcomes’”).

Absent an injunction, the process of matching organs to recipients at transplant centers Buckeye serves will be delayed, decreasing the number of recipients who can receive organs. Seventeen people on the national transplant waiting list die every day waiting for an organ. UNOS desire to impede the work of transplant centers that Buckeye serves so that UNOS can win a debate about what its terms and policies mean is inexcusable. To be sure, maintaining the

³ For that reason, Buckeye respectfully requests that an injunction issue without giving security.

security and privacy of data related to organ donors is essential. But UNOS does not allege that Buckeye's work on behalf of its transplant center customers violates any privacy statute or regulation. To the contrary, following an exhaustive review process over the past two months, UNOS' June 21 letter did not conclude that Buckeye's processes violated HIPAA. If Buckeye were to accede to UNOS' demands that Buckeye stop using its Rapid Organ Assessment Tool and delete data, Buckeye would still have access to the same patient data. But Buckeye personnel would have to manually copy down that data to communicate it to transplant teams—dramatically slowing the process and increasing the risk of inadvertent error. There is no privacy-related reason to permit Buckeye to do the same work with the same data in a far slower and less accurate manner.

CONCLUSION

Buckeye respectfully requests that the Court temporarily and preliminarily enjoin UNOS, as well as its officers, agents, servants, employees, and attorneys, and all other persons who are in active concert or participation with any of them, from (a) requiring Buckeye to cease operation of its Rapid Organ Assessment Tool,⁴ (b) requiring Buckeye to delete data, (c) suspending Buckeye's access to the OPTN, or (d) attempting to monopolize the U.S. market for providing transplant centers with data regarding the centers' past decisions to accept or not accept organs for transplant.

⁴ Buckeye voluntarily paused its use of the Operational Assessment Tool in May. Buckeye does not include the Operational Assessment Tool in its request for a temporary restraining order, although Buckeye does request that any preliminary injunction bar UNOS from prohibiting Buckeye from resuming use of this tool.

Dated: July 3, 2023

Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

I hereby certify that on July 3, 2023, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system and served a copy via email on the following:

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